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Stanislaus Aksman
Hunton & Williams
Suite 1200
1900 K Street, N.W.
Washington, DC 20006

EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT PAPER NUMBER

1655

DATE MAILED: 07/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/853,635	Applicant(s) OLSON, BENGT KRISTER	
	Examiner Dr. Kailash C. Srivastava	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 104-133 is/are pending in the application.
- 4a) Of the above claim(s) 105,107,116,118,119,121-123,128,132 and 133 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 104, 106, 108-115,117, 120, 124-127&129-131 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's response filed 28 April 2006 to election requirement in Office Action mailed 28 March 2006 is acknowledged and entered.
2. Claims 104-133 are pending.
3. Examiner very much appreciates that applicant labels each page of the response referred above with Attorney Docket Number. This practice immensely ameliorates the chances of papers lost during transaction/transmission of paper once a filing/response arrives at the United States Patent and Trademark Office (i.e., USPTO). However, after a response/filing arrives at the USPTO, the claims, remarks, amendments etc., are separated for proper coding to scan them in the electronic file wrapper (i.e., IFW). In order to ensure that all the papers pertaining to a particular application are properly coded in the same application electronic file wrapper, and to further facilitate the prosecution; especially during a telephonic conversation/interview with applicant/applicant's representative, Examiner suggests that in addition to reciting Attorney Docket Number, applicant recites in the header of the each page for any filing/response/amendment, the following information:
 - a. U.S. Non-Provisional application Serial Number (e.g., 09/853,635);
 - b. Filing date for said application;
 - c. First Applicant's name;
 - d. Group Art Unit Number (e.g., 1655);
 - e. Examiner's name (e.g., Dr. Kailash C. Srivastava);
 - f. Document Page number (e.g., Page 1); and
 - g. Date of amendment/response.

Papers/responses filed according to above-stated guidelines immensely ameliorate the chances of papers lost during transaction/transmission, coding, indexing and placing the papers in IFW.

Restriction/Election

4. Applicant's election with traverse of Group I, Claims 104,106,108-115, 117, 120, 124-127 and 129-131 is acknowledged and entered. Applicant's traversal is on following grounds:
 - i. that applicants' non-elected claims, "while patentably distinct " from the claims encompassed in Group I claims that the applicant has elected further prosecution are

related in subject matter to the claims that applicant has elected for further prosecution in the response cited *supra*;

- ii. "According to MPEP, when the claims can be searched and examined together without serious burden, even though the claims are drawn to independent or distinct inventions, the USPTO must examine the claims together on the merits;
- iii. To demonstrate the burden, the USPO must show that the groups have a separate classification, acquired a separate state in the art or searching would require different fields.
- iv. Linking Claim 104, links Groups I-VII not just I-III and VII because components claimed in Claim 104 are also present in the inventions of Groups IV-VI.

Examiner has fully and carefully considered applicant's arguments cited *supra*. Applicant's arguments, however, are not found persuasive because of the reasons of record in items 8-10 on pages 2-4 in Office Action mailed 28 March 2006, and those elucidated below.

Applicant admits on record that the invention of Group I, encompassing Claims 104, 106, 108-115, 117, 120, 124-127 and 129-131 is "distinct" than that Claimed in inventions Of Groups II-VII. Moreover, in the Office Action mailed 28 March 2006, the Examiner has clearly pointed out the Classification (i.e., Class and subclass), state in the art and searching requirements for each of the inventive groups (See Page 4, item 10, Paragraph 2). Furthermore, the burden lies not only in the search of literature, non-patent literature, U.S. and non-U.S. patents, but burden also lies in the examination of the claim language and specification for compliance with the statutes concerning new matter, distinctness and scope of enablement. Clearly different searches and issues are involved with each group. Moreover, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the condition for patentability is different in each case. For these reasons, the restriction requirement is still deemed proper, is adhered to and is made FINAL.

5. Accordingly, Claims 105, 107, 116, 118-119, 121-123, 128 and 132-133 are withdrawn from further consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Examiner suggests that the non-elected claims cited *supra* be canceled in

response to this Office action to facilitate/expedite prosecution.

6. Claims 104, 106, 108-115, 117, 120, 124-127 and 129-131 are examined on merits.

Priority

7. Applicant's claim for foreign priority under 35 U.S.C. § 119(a-d) to Danish Application PA 2000 00782 filed 12 May 2000 is acknowledged.

Objection To Specification

8. The specification is objected to because Line one of first page of specification, in its present form does not properly cite the application priority data. Applicant should indicate at the first line of the first page of the specification that the instant application Claims priority for e.g., to Danish Patent Application, as follows:

"This application Claims Priority to Danish Application PA 2000 00782 filed 12 May 2000."

9. 35 U.S.C. §112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms, which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. §112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are: e.g., Page 7, lines 34-35, "Grape seed of *Vitis vinifera*. *Vitis vinifera* is the taxonomic name for grape, therefore the phrase, "grape seed of *Vitis vinifera*" is redundant because Grape and "*Vitis vinifera*" are both same plants. Another example is, "The tomato variety..... is *Lycopersicum aesculentum*" (See Page 5, Line 24). *Lycopersicum aesculentum* is the botanical name for the tomato plant, not any particular variety of tomato plant. The Examiner suggests that the applicant carefully revises the specification including the abstract to make the specification clearly comprehensible and free of technical/ scientific error(s). Applicants are warned to be careful to not add any new matter while revising the application for corrections to eliminate inexact or verbose terms.

Examiner has not checked the entire specification to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicant may become aware in the specification. Applicant is warned to be careful to not add any new matter while revising the application for corrections to eliminate any verbose or incorrect terms/language.

Claims Objection

10. Claims 104, and 111 are objected to for the reasons noted below:

- In Claim 104, for each one of glycosaminoglycan and polyphenolic, hydrophilic antioxidant, the statement is amended that those components are either synthetic or those obtained from cartilage enzymatic hydrolysis and grape seed respectively. How would one differentiate a given synthetic component/compound from the counterpart of the same compound that is obtained from a natural source?
- In Claim 111, at Line 1, the word --claim--should be inserted after the word, "to".

Appropriate correction/ explanation is required.

All other claims depend directly or indirectly from the objected claims (e.g., Claim 104) and are, therefore, also objected to for the reasons set forth above.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 104, 106, 108-115, 117, 120, 124-127 and 129-131 are rejected under 35 U.S.C. § 103 (a) as obvious over combined teachings from Kosbab (WO 00/07607) in view of Bombardelli et al. (EP 0,6559,402) and Hersh (U.S. Patent 5,906,811).

Claims recite a method to enhance or maintain the collagen synthesis in the dermis comprising orally administering a composition comprising: glycosaminoglycan obtained from cartilage enzymatic hydrolysate or synthetically produced, (ii) hydrophilic antioxidant present in grape seed extract or synthetically obtained, and lycopene. Said composition additionally comprises: *Acerola* extract and beta-carotene.

Kosbab, teaches a method to enhance collagen production in an individual via administering a composition comprising cartilage extract (bovine and shark cartilage) or glycosaminoglycan = chondroitin sulphate (Page 24, Line 6) and antioxidant containing plant extracts (See e.g., Page 8, Lines 3-4), wherein antioxidants are: carotenoid and flavonoids. The

sources for carotenoids in said composition are β -carotene, lutein, lycopene, zeaxanthin (Page 24, Lines 24-25) and sources for flavonoids are: extracts of grape seed (Page 23, Lines 26-32 and Page 24, Lines 10 and 20-21). Kosbab further teaches collagen maintenance (Table 2) with a composition comprising shark cartilage, grape seed extract and lycopene. Kosbab. However, does not explicitly explain that his method and composition comprises procyanidole oligomers and does not teach a method wherein a composition comprising Acerola extract is orally administered to a person in need thereof. Bombardelli et al., teach a composition comprising hydrophilic antioxidants with lycopene, wherein the sources for hydrophilic antioxidants are: proanthocyanidin and procyanidole oligomers extracted from *Vitis vinifera*. Said composition also comprises β -carotene, lycopene and vitamin E wherein tomato is the source of lycopene (Page 6, Lines 47-53 and Page 7, Lines 1-4). Thus, Bombardelli et al. clearly define the sources of hydrophilic antioxidants and lycopene in their composition and further teach that the sources for lycopene and hydrophilic antioxidants comprising their composition are natural. Hersh teaches a method to orally administer a composition comprising acerola extract in addition to beta- carotene, proanthocyanidins from grape seeds (Column 18, Line 61 to Column 19, Line 7). Note that despite Hersh's method not teaching enhancement/maintenance of collagen synthesis, Hersh teaches a method to orally administer the same composition as that elucidated by Kosbob et al. Thus, Hersh intrinsically teaches a method to enhance collagen synthesis/maintenance in an individual because Hersh teaches to administer a composition according to the same steps and comprised of same compositions as those instantly claimed. Thus, both Kosbab and Hersh teach a method to enhance/maintain collagen synthesis via orally administering to an individual in need thereof a composition comprising same components and according to the same steps as are claimed in the instant method invention.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings from Kosbob with beneficial teachings from Bombardelli et al. and Hersh to obtain a method to enhance /maintain collagen synthesis in an individual via orally administering to said individual a composition comprising (i) glycosaminoglycan obtained from cartilage enzymatic hydrolysate or synthetically produced, (ii) hydrophilic antioxidant present in grape seed extract or synthetically obtained, and (iii) lycopene, (iv) beta carotene and (v) acerola extract, because Kosbob teaches a method to administer a composition comprising glycosaminoglycan, hydrophilic antioxidant present in grape seed extract, lycopene and beta carotene, Bombardelli et al. teach a composition

comprising the same components as those taught by Kosbob and in addition teach that procyanidole oligomers are present in *Vitis vinifera* (i.e., grape seed extract) and Hersh who additionally teaches acerola extract in his composition. The concentration of individual antioxidant components or of components obtained from cartilage/cartilage extract in the aforementioned prior art references is either not disclosed or is not the same as in the claimed invention. However, the adjustment of particular conventional working conditions (e.g., concentrations of individual components comprising a given composition or ratios among different components of a composition) is deemed merely a matter of judicious selection and routine optimization of a result oriented parameter, which is well within the purview of the skilled artisan.

One having ordinary skill in the art at the time the invention was made would have been motivated to combine the teachings from Kosbob with beneficial teachings from Bombardelli et al. and Hersh to obtain a method to enhance /maintain collagen synthesis in an individual via orally administering to said individual a composition comprising (i) glycosaminoglycan obtained from cartilage enzymatic hydrolysate or synthetically produced, (ii) hydrophilic antioxidant present in grape seed extract or synthetically obtained, and (iii) lycopene, (iv) beta-carotene and (v) acerola extract, because as discussed above, Bombardelli et al., remedy the deficiency in Kosbob's teachings of procyanidole oligomers and Hersh remedies the deficiency of acerola extract in the teachings from Kosbob.

From the teachings of the references cited *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claim Rejections Under 35 U.S.C. § 112

13. The following is a quotation of the second paragraph of 35 U.S.C. § 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

14. Claim 115 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 115 is improperly dependent on a Claim that is numbered later than (i.e., Claims 127 and 1129) Claim 115. The applicant should correct the pendency for Claim 115.

Reply To Applicant's Arguments Filed In Response To Final Rejection

15. In response to applicant's amendment, cancellation of Claims 1-103 and arguments presented along with the RCE filed 28 December 2005, the Examiner hereby withdraws the objections/ restrictions in the Final rejection mailed 28 January 2005. This is because with the establishment of RCE (See Office Action mailed 28 March 2006), the finality of the Office Action mailed 28 January 2005 has been withdrawn.


Conclusion

16. For aforementioned reasons, no Claims are allowed.


17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey, can be reached on (571)-272-0775 Monday through Friday 8:30 A.M. to 5:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.


Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1655
(571) 272-0923

July 23, 2006


RALPH GITOMER
PRIMARY EXAMINER
GROUP 1200